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09/834,312	04/13/2001	Lisbeth Illum	8567-603US (WESR/P21598US)	2569

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2005 MARKET STREET, SUITE 2200  
PHILADELPHIA, PA 19103-7013

EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 06/18/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/834,312

Applicant(s)

ILLUM ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 7,20,21 and 28-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7,20,21 and 28-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Examiner acknowledges receipt of request for extension of time and amendment C filed 03/25/03. Claims 7, 20, 21 and 28-39 are pending.

#### ***Claim Rejections - 35 USC § 112***

1. The rejection of claims 5 and 26 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn because claims 5 and 26 are cancelled by the amendment filed 03/25/02.
2. The rejection of claim 5 and 26 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn because claims 5 and 26 are cancelled.

#### ***Claim Rejections - 35 USC § 102***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. The rejection of claims 1-3, 14, 20-22, 30 and 33 under 35 U.S.C. 102(e) as being anticipated by Wong et al. (US 6,120,803) is withdrawn because claims 1-3, 14 and 22 are cancelled claims 20, 21, 30 and 33 depend from new claims 34 and 35 that the prior art no longer read on.
5. The rejection of claims 1-3, 12-14 and 20 under 35 U.S.C. 102(e) as being anticipated by Lech (US 6,027,746) is withdrawn because claims 1-3, 12-14 are cancelled and claim 20 depends on new claim 34 that the prior art no longer reads on.

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6. The rejection of claims 1-3, 12-14 and 20 under 35 U.S.C. 102(e) as being anticipated by Ahlgren et al. (US 6,117,452) is withdrawn because claims 1-3, 12-14 are cancelled and claim 20 depends on new claim 34 that the prior art no longer reads on.

7. The rejection of claims 1-3, 9-11, 14, 20-22 and 33 under 35 U.S.C. 102(a) as being anticipated by pages 1189 to 1190 of 1998 physician desk reference is withdrawn because claims 1-3, 9-11, 14 and 22 are cancelled and claims 20, 21 and 33 depends of new claim 34 that the prior art no longer reads on.

8. Claim 34 is rejected under 35 U.S.C. 102(b) as being anticipated by Carr et al. (US 4,254,129).

Carr discloses a composition comprising 0.01 to 20 mg/kg of body of a piperidine derivative of which fexofenadine is one, and carrier where the carrier can be propylene glycol or polyethylene glycol (column 5, lines 23 and 51-59. Instant claim 34 is a composition claim and future intended use and route of administration are not critical in a composition claim. The teaching of Carr meets the limitations of the claims.

9. Claims 28, 29, 34, 35, 37 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Conte et al. (EP 0 468 392).

Conte prepares a pharmaceutical composition that shows increased active substance dissolution (abstract) and the composition comprises terfenadine (fexofenadine), beta-cyclodextrin, hydroxypropylmethylcellulose (gelling agent) and the amount Terfenadine is about 23% (example 13b). Example 14 of Conte comprises Terfenadine (about 26%), beta-cyclodextrin, polyvinylpyrrolidone, corn- starch (gelling agent) and magnesium stearate. These

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compositions are aqueous based. Future intended use and the route of administration is not critical in a composition claim. The teachings of Conte meet the limitations of the claims.

10. Claim 34 is rejected under 35 U.S.C. 102(b) as being anticipated by Chiesi et al. (WO 94/16733).

Chiesi discloses a composition that comprises terfenadine and cyclodextrin (example 2). Chiesi suggests that hydroxypropyl beta-cyclodextrin may be a preferred cyclodextrin for solubilizing amine drugs such as terfenadine (page 2, lines 4-15). Instant claim 34 is a composition claim and future intended use and route of administration are not critical in a composition claim. Thus, Chiesi meets the limitations of the claims.

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 7 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conte et al. (EP 0 468 392) in view of Chiesi et al. (WO 94/16733).

Conte clearly teaches a pharmaceutical composition comprising terfenadine, beta-cyclodextrin, carrier and gelling agent as discussed above. But Conte does not teach hydroxypropyl-beta-cyclodextrin.

But Chiesi teaches that terfenadine can be formulated with hydroxypropyl-beta-cyclodextrin to enhance the solubility as discussed above.

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Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a pharmaceutical composition comprising terfenadine, beta-cyclodextrin, carrier and gelling agent according to the teaching of Conte. One having ordinary skill in the art would have been motivated to modify the composition of Conte by formulating the terfenadine pharmaceutical composition with hydroxypropyl-beta-cyclodextrin as taught by Chiesi with the expectation that the solubility of terfenadine will be enhanced.

13. Claims 20, 21, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conte et al. (EP 0 468 392) in view of Badwan et al. (US 5,646,131).

Conte clearly teaches a pharmaceutical composition comprising terfenadine, beta-cyclodextrin, carrier and gelling agent as discussed above. But Conte is silent on administering the composition to a person in need thereof to treat rhinitis.

But Badwan teaches a composition comprising terfenadine and cyclodextrin and the composition is administered to a person in need thereof to treat rhinitis (column 3, lines 22-30, column 4, line 47 and column 6, lines 30-44).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a pharmaceutical composition comprising terfenadine, beta-cyclodextrin, carrier and gelling agent according to the teaching of Conte. One having ordinary skill in the art would have motivated to administer the terfenadine pharmaceutical composition of Conte to a person in need thereof with the expectation that the terfenadine composition would treat rhinitis as disclosed by Badwan.

14. Claims 30, 33 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conte et al. (EP 0 468 392) in view of Clancy et al (WO 97/02017).

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Conte clearly teaches a pharmaceutical composition comprising terfenadine, beta-cyclodextrin, carrier and gelling agent as discussed above. But Conte does not teach a composition that contains terfenadine and poloxamer block copolymer. However, Clancy discloses formulating terfenadine with hydrophilic poloxamer block copolymer and this composition is sustained release (abstract). Thus, Clancy is relied upon for a teaching where terfenadine can be formulated with poloxamer.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a pharmaceutical composition comprising terfenadine, beta-cyclodextrin, carrier and gelling agent according to the teaching of Conte. One having ordinary skill in the art would have been motivated to substitute one solubility enhancing excipient with another, in this case a cyclodextrin with poloxamer, with the expectation that the solubility of terfenadine will be improved as disclosed by Clancy.

Other matters:

Claims 34 and 35 have "tetraglycol" in parenthesis after "glycofurol" and it appears to give the interpretation that tetraglycol is another name for glycofurol. However, a file registry search on STN appears to indicate that tetraglycol and glycofurol are not the same chemical and the two chemicals have different registry numbers. Correction is respectfully requested.

No claim is allowed.

15. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara  
June 15, 2003

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600  
